

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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UNITED STATES OF AMERICA

- v. -

LAURENCE F. DOUD III,

Defendant.

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19 Cr. 285 (GBD)

**GOVERNMENT’S MEMORANDUM OF LAW IN OPPOSITION TO
DEFENDANT LAURENCE F. DOUD III’S
MOTION TO DISMISS COUNT ONE OF THE INDICTMENT**

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PRELIMINARY STATEMENT

The Government respectfully submits this memorandum of law in opposition to defendant Laurence F. Doud III's motion to dismiss Count One of Indictment 19 Cr. 285 (GBD) (the "Indictment") ("Mot."). The defendant was the chief executive officer ("CEO") of a major pharmaceutical distribution company that sold dangerous and highly addictive drugs, like oxycodone and fentanyl, that the defendant knew were being dispensed illicitly to individuals who had no legitimate medical need for them, and who were instead selling or abusing the drugs. The defendant and his company made millions through this scheme, and in the process helped to saturate the country with staggering quantities of illicit oxycodone and fentanyl.

And now he wants a free pass for his drug dealing. He argues that, because of his status as a CEO, he was too far removed from the "front line of the prescription process" to be subject to the laws that apply to every other person who participates in the illegal sale of controlled substances outside of their approved medical use. (Mot. at 2.) This illogical argument has no basis in either statutory language or case law, and flies in the face of 40 years of precedent holding that the federal narcotics laws apply without regard to "the status of the defendant." *United States v. Moore*, 423 U.S. 122, 134 (1975). A pharmaceutical CEO is not immune from criminal liability simply because he conspired to distribute controlled substances from an office suite rather than a street corner. The defendant's scheme to unlawfully distribute controlled substances not for legitimate medical purposes fits squarely within the conduct that Sections 841 and 846 of Title 21 proscribe. His motion to dismiss Count One of the Indictment is without merit and should be denied.

BACKGROUND

I. The Indictment

The Indictment charges the defendant in two counts. First, it charges the defendant with conspiring with others to distribute and possess with the intent to distribute controlled substances outside the scope of professional practice and not for a legitimate medical purpose, in violation of Title 21, United States Code, Sections 846, 841(a)(1), 841(b)(1)(A), and 841(b)(1)(C) (Count One). Second, it charges the defendant with conspiring to defraud the United States, in violation of Title 18, United States Code, Section 371 (Count Two). The defendant's motion seeks dismissal of Count One of the Indictment only.

II. Offense Conduct

With respect to Count One, the Indictment describes a five-year-long scheme in which the defendant conspired to violate the narcotics laws by distributing controlled substances to pharmacies that the defendant knew were selling those drugs for unlawful purposes.

As alleged in the Indictment, the defendant was the CEO of Rochester Drug Co-Operative, Inc. ("RDC") from September 1991 through April 2017. (Indictment ¶ 1.) RDC was the fourth largest wholesale pharmaceutical distributor in New York State, and among the nation's ten largest pharmaceutical distributors. (*Id.* ¶ 2.) As a pharmaceutical distributor, RDC was responsible for distributing non-prescription and prescription drugs – including controlled substances – to pharmacy customers. (*See id.* ¶¶ 8-9.) During the defendant's tenure as RDC's CEO, RDC supplied tens of millions of doses of opioids, including oxycodone and fentanyl, to pharmacies that the defendant knew were dispensing those drugs to individuals with no legitimate medical need for them. (*Id.* ¶ 3.)

As of at least 2014, the defendant was aware of the opioid abuse epidemic plaguing the United States and the role of prescription opioids like oxycodone and fentanyl in fueling that

epidemic. (*Id.* ¶ 6.) The defendant also was aware of RDC’s obligations as a registrant with the Drug Enforcement Administration (“DEA”) to implement sufficient controls against prescription drug diversion including by, among other things, not shipping controlled substances to pharmacies that were dispensing those drugs unlawfully. (*Id.* ¶¶ 7-12.)

The defendant nevertheless agreed to distribute controlled substances to pharmacies that displayed an array of “red flags” of diversion. (*Id.* ¶ 14.) For example, in 2012, RDC began supplying what became its largest pharmacy customer (“Pharmacy-1”). Pursuant to RDC’s own policies, RDC placed a cap on how much oxycodone and fentanyl Pharmacy-1 could order from RDC in a given month. But when Pharmacy-1 rapidly began exceeding those limits, the defendant directed his employees to release Pharmacy-1’s orders for shipment anyway. Even when Pharmacy-1 refused to provide RDC with data RDC needed to verify the legitimacy of its controlled substance orders, the defendant ordered his employees to ship. (*Id.* ¶ 16.) He agreed to keep shipping controlled substances to Pharmacy-1, even though he understood that those substances were being sold outside of any legitimate medical purpose, in order to maximize RDC’s revenues and his own personal compensation, which was directly tied to RDC’s revenues. (*Id.* ¶ 13.)

The defendant engaged in this unlawful diversion through RDC’s dealings with numerous other pharmacy customers, as well. To take another example, as early as 2013, RDC’s head of sales informed the defendant that “we have some VERY suspicious customers due to their buying” of large quantities of controlled substances. (*Id.* ¶ 17.) Despite specific and repeated warnings like this, at the direction of the defendant, RDC continued to supply such customers with controlled substances – some of which customers in turn were filling prescriptions for physicians on a “watch list” that RDC employees had created to keep track of doctors who appeared to be diverting

controlled substances. (*Id.*) The defendant and RDC were even aware that the DEA was investigating some of those doctors. Yet the defendant agreed to continue distributing pills for the eventual use by those doctors' supposed "patients," and directed his employees at RDC accordingly. (*Id.*) Simply put, the defendant participated in a scheme to sell massive quantities of dangerous and highly addictive controlled substances for recreational use so that he and his company could make money.

ARGUMENT

I. The Indictment Properly Alleges a Violation of 21 U.S.C. § 846

The Controlled Substances Act ("CSA") prohibits "any person" from knowingly or intentionally distributing a controlled substance or conspiring to do the same. The defendant argues, without any basis in law or logic, that because he held a high-level corporate position at a pharmaceutical distribution company, he is somehow insulated from criminal liability for the unlawful distribution of narcotics. He is incorrect. The CSA applies not just to street-level drug dealers, but also to pharmacists, doctors, drug distributors, and drug manufacturers acting outside of the legitimate distribution chain. As the CEO of RDC, the defendant directed the sale of dangerous and addictive controlled substances that he knew were being dispensed illicitly to individuals who had no legitimate medical need for them. Because such conduct is clearly unlawful under the CSA, the well-pleaded allegations in the Indictment are sufficient under Federal Rule of Criminal Procedure 7. Accordingly, the Court should deny the defendant's motion to dismiss.

A. Applicable Law

1. Motion to Dismiss Standard

“A criminal defendant is entitled to an indictment that states the essential elements of the charge against him.” *United States v. Pirro*, 212 F.3d 86, 91 (2d Cir. 2000) (citing *Jones v. United States*, 526 U.S. 227, 232 (1999)); *Hamling v. United States*, 418 U.S. 87, 117 (1974); Fed. R. Crim. P. 7(c)). “A defendant faces a ‘high standard’ in seeking to dismiss an indictment.” *United States v. Thompson*, 13 Cr. 378 (AJN), 2013 WL 6246489, at *6 (S.D.N.Y. Dec. 3, 2013) (quoting *United States v. Post*, 08 Cr. 243 (KMK), 2013 WL 2934229, at *5 (S.D.N.Y. June 3, 2013)). “[A]n indictment is sufficient if it, first, contains the elements of the offense charged and fairly informs a defendant of the charge against which he must defend, and, second, enables him to plead an acquittal or conviction in bar of future prosecutions for the same offense.” *Hamling*, 418 U.S. at 117. “An indictment must be read to include facts which are necessarily implied by the specific allegations made.” *United States v. LaSpina*, 299 F.3d 165, 177 (2d Cir. 2002) (internal quotation marks omitted).

“[T]he sufficiency of the evidence is not appropriately addressed on a pretrial motion to dismiss an indictment.” *United States v. Alfonso*, 143 F.3d 772, 777 (2d Cir. 1998). Accordingly, “[i]n reviewing a motion to dismiss an indictment, the Court must take the allegations of the indictment as true.” *United States v. Skelos*, 15 Cr. 317 (KMW), 2015 WL 6159326, at *2 (S.D.N.Y. Oct. 20, 2015) (citing *Boyce Motor Lines v. United States*, 342 U.S. 337, 343 n.16 (1952)).

2. The Controlled Substances Act

Under the CSA, it is a crime “for any person knowingly or intentionally to . . . distribute, . . . or possess with intent to . . . distribute . . . a controlled substance,” 21 U.S.C. § 841,

or to conspire to do the same, 21 U.S.C. § 846. There is a narrow exception to this blanket prohibition on the distribution of controlled substances for certain individuals and entities. As set forth in Section 822, “[p]ersons registered by the Attorney General,” who are known as “registrants,” may “possess, manufacture, distribute, or dispense [controlled] substances . . . to the extent authorized by their registration and in conformity with the other provisions of this subchapter.” *Id.* § 822(b). In other words, “only the lawful acts of registrants are exempted” from criminal liability under Sections 841 and 846. *United States v. Moore*, 423 U.S. 122, 131 (1975).

The DEA’s regulations, promulgated pursuant to 21 U.S.C. § 821, contain further limitations on the rights of registrants and their agents and employees to distribute controlled substances. *See* 21 U.S.C. § 821 (“The Attorney General is authorized to promulgate rules and regulations . . . relating to the registration and control of the manufacture, distribution and dispensing of controlled substances. . . .”). DEA regulations require registrants to maintain effective controls against the diversion of controlled substances, including but not limited to a suspicious order reporting system. 21 C.F.R. §§ 1301.71(a), 1301.74(b). Doctors and pharmacists, who must individually register with the DEA to dispense controlled substances, must ensure “proper prescribing and dispensing of controlled substances.” *Id.* § 1306.04(a). They may issue controlled substance prescriptions only “for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.” 21 C.F.R. § 1306.04(a).

The Supreme Court in *United States v. Moore* first addressed the question whether a registrant is subject to prosecution under Section 841, holding in a unanimous opinion that registrants have no special immunity from prosecution by virtue of their status. 423 U.S. 122 (1975). *Moore* involved a doctor who was charged under Section 841 for unlawfully distributing Methadone. Like the defendant here, the defendant in *Moore* claimed blanket immunity from

prosecution under Section 841, and that other, more lenient statutes, were designed to address his conduct. The Supreme Court’s reasoning in rejecting this argument is highly instructive here, and as explained below, conclusively counsels in favor of denying the defendant’s motion.

Moore recognized that “[b]y its terms § 841 reaches ‘any person.’ It does not exempt (as it could have) ‘all registrants’ or ‘all persons registered under this Act.’” 423 U.S. at 131. As a result, “only the *lawful* acts of registrants are exempted” from prosecution under Section 841. *Id.* (emphasis added). This reasoning was grounded in the CSA’s legislative history indicating “that Congress was concerned with the nature of the drug transaction, rather than with the status of the defendant.” *Id.* at 134. To address this concern, the CSA made any “transactions outside the legitimate distribution chain illegal.” *Id.* at 135 (quoting H.R. Rep. No. 91-1444, p. 3). Certain provisions, like Sections 842 and 843, impose lesser penalties for “[m]ore or less technical violations” by registrants. *Id.* (quoting H.R. Rep. No. 91-1444, p. 10). In parallel to these lesser penalties, Sections 841 and 846 impose “‘severe criminal penalties’ . . . on those, like respondent, who sold drugs, not for legitimate purposes, but ‘primarily for the profits to be derived therefrom.’” *Id.* (quoting H.R. Rep. No. 91-1444, p. 10).

The implementation of this liability scheme was entirely sensible given that “registrants, who have the greatest access to controlled substances and therefore the greatest opportunity for diversion, were responsible for a large part of the illegal drug traffic.” *Id.* (citation omitted). To categorically exempt them from prosecution under the statutes specifically aimed at curtailing illegal drug trafficking would have directly undercut Congress’ purpose in enacting the CSA. The *Moore* Court was particularly concerned with the defendant’s argument that registrants were categorically exempt from prosecution under Section 841 because it would exempt not just physicians, like Moore, but “[i]t would even compel exemption from the provisions of § 841 of all

‘registrants,’ including manufacturers, *wholesalers*, and pharmacists in addition to physicians.” *Id.* at 143 (emphasis added). Thus, the *Moore* Court specifically rejected the notion that wholesale distributors should be exempt from the provisions of Section 841 – precisely the notion that the defendant seeks to recapitulate here, without supporting legal authority.

Following *Moore*, this Circuit has affirmed that “a physician has no special license to divert the flow of drugs from legitimate medical distribution to illicit commercial trade and that if he does so he may be prosecuted under § 841(a) since he then acts as a ‘drug pusher’ rather than as a medical professional.” *United States v. Vamos*, 797 F.2d 1146, 1152 (2d Cir. 1986) (citing *Moore*, 423 U.S. at 138). The “added responsibilities” imposed on physicians by the CSA “are essential to protect the public against abuse by ‘registrants, who have the greatest access to controlled substances and therefore the greatest opportunity for diversion.’” *Id.* at 1153 (quoting *Moore*, 423 U.S. at 135). Nor is liability for diversion under the CSA limited to doctors and pharmacists. For example, “[a] lay defendant likewise may be convicted of unlawful distribution of a controlled substance where the defendant relies upon a doctor’s prescription that he knows or reasonably should have known was invalid.” *United States v. Quinones*, 635 F.3d 590, 594 (2d Cir. 2011) (citing *Vamos*, 797 F.2d at 1153).

B. The Defendant Is a “Person” Subject to Criminal Liability Under 21 U.S.C. §§ 841 and 846

The plain language of the CSA, as well as binding precedent, demonstrate that the CEO of a pharmaceutical distribution company, such as the defendant, may be prosecuted under Sections 841 and 846. One need not look beyond the plain language of Section 841 to reach this ineluctable conclusion. Section 841 assigns criminal liability to “any person” who knowingly or intentionally possesses with the intent to distribute or distributes a controlled substance. Section 846 adds that “[a]ny person who . . . conspires to commit any offense” under Section 841 shall be guilty of a

crime. The defendant indisputably is a “person.” The defendant therefore is subject to prosecution under these statutes absent application of an exception.

The defendant, seeking such an exception, argues that a pharmaceutical CEO is categorically exempt from prosecution under Sections 841 and 846. (*See* Mot. at 9-11, 16-23.) As set forth above, the Supreme Court in *Moore* directly addressed and rejected the claim that a defendant could be immune from prosecution under Section 841 by virtue of his status. The defendant attempts to distinguish *Moore* on the basis that it addressed a physician, rather than a pharmaceutical executive. (*See* Mot. at 20.) But *Moore*’s reasoning plainly extends to any person within the controlled substances distribution chain – the defendant included. The Court could not have been clearer that the status of the defendant is immaterial to the application of Section 841. The only question relevant to the application of Section 841 is whether the controlled substance transactions at issue were within the legitimate distribution chain. Here, as alleged in the Indictment, they were not.

Further undercutting the defendant’s attempts to distinguish *Moore* is the Court’s express concern, underlying its holding, that a contrary result would exempt manufacturers and wholesalers from liability under Section 841. The Court cautioned that accepting the defendant’s interpretation of Section 841 “would even compel exemption from the provisions of § 841 of all ‘registrants,’ including manufacturers, wholesalers, and pharmacists in addition to physicians.” *Moore*, 423 U.S. at 143. Rather than give manufacturers, wholesalers, pharmacists, and physicians carte blanche to distribute dangerous controlled substances to anyone, for any reason – or no reason at all – without the possibility of facing the same criminal penalties any other drug dealer would face, the Supreme Court concluded that the CSA only “authorizes transactions within ‘the

legitimate distribution chain’ and makes all others illegal.” *Id.* at 140 (quoting H.R. Rep. No. 91-1444, p. 3).

Courts repeatedly have relied on *Moore* in rejecting defendants’ attempts to invoke the very exemption from liability to which this defendant claims entitlement. For example, the Ninth Circuit in *United States v. Goldfine* rejected the argument that a non-registrant pharmacy employee “is authorized to possess controlled substances” as an employee of a registrant and therefore “should be free from prosecution under § 841.” 538 F.2d 815, 819 (9th Cir. 1976). Quoting *Moore*, the Ninth Circuit reasoned that “[b]y its terms § 841 reaches ‘any person’” – including the employee of a registrant. *Id.* (quoting *Moore*, 423 U.S. at 131). The Sixth Circuit similarly rejected a non-registrant medical center employee’s contention that he was exempt from prosecution under Section 841 because “he does not fit within the category of physicians which, under *Moore*, were excluded from the exception for practitioners registered under section 822.” *United States v. Johnson*, 831 F.2d 124, 128 (6th Cir. 1987) (explaining that “[p]roceeding from this assumption, [the defendant] then reaches the dubious conclusion that he is not subject to the general rule. The weakness of this argument is apparent.”); *see also United States v. Quinones*, 536 F. Supp. 2d 267, 270-71 (E.D.N.Y. 2008) (holding that non-registrant Internet pharmacy owners may be prosecuted under Section 841); *Correa v. United States*, 92 Civ. 6637 (PKL), 1992 WL 380555, at *4-5 (S.D.N.Y. Dec. 4, 1992) (rejecting the non-registrant defendant’s claim that Section 841 applies only to physicians), *aff’d*, 9 F.3d 1537 (2d Cir. 1993).

Contrary to the defendant’s suggestion, these decisions have not “expanded” Section 841 “to apply to the medical and pharmacy professions and those directly linked to them.” (Mot. at 1.) They have instead consistently rejected defendants’ attempts to *narrow* Section 841’s broad language to categorically exclude certain classes of individuals from its scope – exactly what the

defendant here attempts to do. There simply is no support in the law for the defendant's claim that because of his specific position in the pharmaceutical distribution chain, he should receive different and more lenient treatment under the law than the "street level" dealers he repeatedly references in his brief. (*See* Mot. at 11.) To the contrary, courts consistently have concluded that it is "obvious" that Section 841 applies equally to those who divert controlled substances from the legitimate supply chain and to everybody else, because "[t]he statute's language simply makes it a crime 'knowingly or intentionally' to 'distribute or dispense' narcotic drugs." *United States v. Limberopoulos*, 26 F.3d 245, 249 (1st Cir. 1994).

The statutory language and case law discussed above belie the defendant's unsupported assertion that "it is well established that the scope of prosecutions under 21 U.S.C. § 841 only reaches doctors, pharmacists and their associates." (Mot. at 16.) There is no basis in statute, case law, or common sense for the defendant's proposal to specially exclude from liability under Sections 841 and 846 the employee of an upstream registrant (such as a manufacturer or distributor) who unlawfully distributes controlled substances. Indeed, the Eighth Circuit rejected a similar argument by the employee of a registrant in *United States v. Hill*, 589 F.2d 1344 (8th Cir. 1979). In *Hill*, the defendant employee was – similar to the defendant here – an employee of a pharmaceutical manufacturer. 589 F.2d at 1350. The defendant was convicted under Section 841 of unlawfully distributing a controlled substance that his employer manufactured. *Id.* at 1348. The defendant appealed, arguing that because of his position and his employer's acceptance of his conduct, "section 841(a)(1) [was therefore] not applicable to him." *Id.* at 1350. In upholding the defendant's conviction under Section 841, the Eighth Circuit reasoned that even if the defendant's employer had tolerated his conduct, "neither the authorization of the action for the sales personnel of a pharmacal company nor the exemption in 21 U.S.C. § 822 legitimizes illegal activities." *Id.*

In other words, distributing controlled substances outside of the “legitimate distribution chain” is always illegal under Section 841, regardless of the defendant’s status or the acquiescence of the defendant’s employer. *See Moore*, 423 U.S. at 141.

Finally, the defendant misconstrues the factual allegations against him in arguing for dismissal of the Indictment. He claims that his alleged conduct consists of “deliberately decid[ing] not to investigate, monitor, or report to the DEA, pharmacy customers that he knew were diverting controlled substances for illegitimate use.” (Mot. at 8.) To be sure, the defendant’s failure to investigate, monitor, and report diverting customers is relevant to and probative of his guilt on Count One. But this is far from the full extent of his conduct. As alleged, the defendant “directed RDC’s continued distribution of controlled substances to . . . pharmacy customers that he knew were dispensing narcotics for illicit purposes.” (Indictment ¶ 19.) The defendant did so in concert with others, both within and outside of RDC, and in so doing engaged in a years’ long conspiracy to distribute, and possess with the intent to distribute, controlled substances for purposes that he knew were outside of legitimate medical use. Count One therefore properly alleges this illegal conduct.

C. Count One Appropriately Charges the Object of the Conspiracy

In addition to arguing, as discussed above, that a person of his professional status and placement in the distribution chain is essentially too high up the corporate ladder to be charged with narcotics trafficking, the defendant takes issue with the object of the narcotics conspiracy in which he is charged. The Indictment charges that the object of the conspiracy in which the defendant participated was to distribute and possess with the intent to distribute controlled substances “outside the scope of professional practice and not for a legitimate medical purpose.” (Indictment ¶ 21.) This means exactly what it says – that the defendant agreed with other people

to distribute and possess with the intent to distribute controlled substances that the defendant knew would be used outside the scope of professional practice and not for a legitimate medical purpose. It does not, as the defendant contends, impose on him any obligations reserved for those with specialized medical knowledge.

Specifically, the defendant complains that he lacked sufficient knowledge of whether the controlled substances with which RDC was flooding the market were required for legitimate medical use to be held accountable for their illicit distribution. (*See, e.g.*, Mot. at 22-23.) There are two fundamental flaws with this argument, each of which is dispositive. First, the question of the defendant's criminal intent is properly left for the jury. *See, e.g., United States v. Heras*, 609 F.3d 101 (2d Cir. 2010) (vacating judgment of acquittal under Rule 29 where there was enough evidence for reasonable jury to infer that defendant had criminal intent and agreed to facilitate drug-trafficking conspiracy). The defendant will of course be free to argue to the jury that the evidence presented at trial does not establish that he knowingly participated in the charged conspiracy. But he is not entitled to a pretrial ruling that the Government lacks sufficient evidence to prove his criminal intent. *See, e.g., Alfonso*, 143 F.3d at 777 (“[T]he sufficiency of the evidence is not appropriately addressed on a pretrial motion to dismiss an indictment.”).

Second, and separately, the defendant's argument that he falls under an exception to the prohibitions of the CSA for agents or employees of registered distributors because he (purportedly) did not know that the controlled substances were being distributed outside of a legitimate medical purpose (*see* Mot. at 11-12), relates to a potential defense, not to an element of the crime that the Government must include in its pleadings. As such, it cannot provide the basis for a motion to dismiss an allegation in the Indictment. Section 885 of Title 21 directs that:

It shall not be necessary for the United States to negative any exemption or exception set forth in this subchapter in any . . . indictment . . . or in any trial,

hearing, or other proceeding under this subchapter, and the burden of going forward with the evidence with respect to any such exemption or exception shall be upon the person claiming its benefit.

21 U.S.C. § 885(a)(1).

Most courts interpreting this provision have concluded that “all exceptions to the prohibition against manufacturing, distributing, dispensing, and possessing controlled substances, are defenses not elements, and . . . their inapplicability need not be alleged in [an] indictment.” *United States v. Steele*, 147 F.3d 1316, 1320 (11th Cir. 1998); *see also United States v. Polan*, 970 F.2d 1280, 1282 (3d Cir. 1992); *United States v. Seelig*, 622 F.2d 207, 211-12 (6th Cir. 1980); *United States v. Roy*, 574 F.2d 386, 391 (7th Cir. 1978). *But see United States v. Hurwitz*, 459 F.3d 463, 475 (4th Cir. 2006); *United States v. King*, 587 F.2d 956, 962-65 (9th Cir. 1978). Thus, the Indictment need not even have specifically alleged as part of the object of the conspiracy charged in Count One that the distribution of controlled substances was “outside the scope of professional practice and not for a legitimate medical purpose.” (Indictment ¶ 21.) The voluntary inclusion in an indictment of language negating an affirmative defense is not a basis for dismissal. *See generally* Fed. R. Crim P. 12; *Roy*, 574 F.2d at 391 (“An indictment founded on a general provision of a statute need not negative an exception made by a proviso or other distinct clause Addition of such language, therefore, should not render an indictment defective.”).

Moreover, even assuming that this language *were* instrumental to the validity of Count One, it was properly pleaded here. Any individual involved in the pharmaceutical distribution chain who distributes a controlled substance “rel[ying] upon a doctor’s prescription that he knows or reasonably should have known was invalid” may be convicted under Section 841. *Quinones*, 635 F.3d at 594. The Second Circuit in *Quinones* applied this standard to the non-registrant owners of an online pharmacy, who could no more be assigned specific medical knowledge than the

defendant. This standard is entirely consistent with the CSA and *Moore*, which make clear that people in the pharmaceutical distribution chain are only authorized to distribute controlled substances for legitimate medical purposes. *See Moore*, 423 U.S. at 131-35. When someone in that system *knowingly* distributes controlled substances not for legitimate medical purposes, that action violates Section 841 regardless of where within the chain that person sits. Just as the pharmacy owners in *Quinones* did not need specialized medical knowledge to know that their pharmacies were filling illegitimate prescriptions, the defendant did not need specialized medical knowledge to direct that RDC stop distributing controlled substances to doctors that his own compliance department had flagged as diverters.

Once again, the defendant's arguments throughout his motion that he did not know and could not have known that the prescriptions RDC's pharmacy customers filled were illegitimate (*see, e.g.*, Mot. at 11, 22), relate to defenses he may raise with the jury at trial, but do not provide the grounds for a motion to dismiss. The Indictment alleges, and the grand jury found, that the defendant "intentionally and knowingly" entered into a conspiracy to violate the narcotics laws. This is all that is required.

D. The Defendant's Remaining Arguments Are Without Merit

The defendant also argues that the existence of other statutes and regulations that potentially apply to his conduct somehow implicitly forecloses the application of Sections 841 and 846. (*See* Mot. at 11-16.) This argument is easily rejected. It is axiomatic that "when an act violates more than one criminal statute, the Government may prosecute[] under either so long as it doesn't discriminate against any class of defendants." *United States v. Batchelder*, 442 U.S. 114, 123-24 (1979). The "defendant has no constitutional right to elect which of two applicable federal statutes shall be the basis of his indictment and prosecution." *Id.* at 125; *see also United*

States v. Graham, 632 F. App'x 4, 7 (2d Cir. 2015) (a defendant does not have the right to “elect how the government charges his criminal conduct or the penalty scheme under which he is sentenced”); *Mannix v. Phillips*, 619 F.3d 187, 200 (2d Cir. 2010) (“[N]o clearly established constitutional prohibition of statutory vagueness is violated when two statutes proscribe the same conduct and a defendant is charged under the one subjecting him to greater punishment”); *United States v. Motta*, 15 Cr. 173 (NSR), 2015 WL 4692462, at *1 (S.D.N.Y. Aug. 6, 2015) (where the defendant’s conduct falls within the scope of two statutes, the government may choose to charge under either); *United States v. Ulbricht*, 31 F. Supp. 3d 540, 560 (S.D.N.Y. 2014) (“How a defendant is charged is within the discretion of the prosecution”).

The defendant in *Moore* raised this identical argument, claiming that the Government could only prosecute him under regulatory provisions like Sections 842 and 843. In rejecting it, the Supreme Court explained that it is “immaterial whether [a defendant] could have been prosecuted for his violation of statutory provisions relating to dispensing procedures. There is nothing in the statutory scheme or the legislative history [of the CSA] that justifies a conclusion that a registrant who may be prosecuted for the relatively minor offense of violating [a regulatory provision] is thereby exempted from prosecution under § 841 for the significantly greater offense of acting as a drug ‘pusher.’” *Moore*, 423 U.S. at 138. The defendant’s contention that Count One must be dismissed because statutes other than Sections 841 and 846 could also be used to impose criminal and regulatory penalties for his conduct therefore plainly fails.

Similarly, it is entirely immaterial to the validity of Count One that the Government has pursued regulatory actions against pharmaceutical companies in the past. (*See Mot.* at 15-16.) It is true that “persons who engage in legitimate transactions must be registered and are subject to penalties under §§ 842 and 843 for ‘[m]ore or less technical violations.’” *Moore*, 423 U.S. at 135.

But at the same time, “‘severe criminal penalties’ [are] imposed on those . . . who s[ell] drugs, not for legitimate purposes, but ‘primarily for the profits to be derived therefrom.’” *Id.* The Government is permitted to assess the facts of a particular case and determine whether they constitute “more or less technical violations,” warranting civil or less severe criminal charges, or illegitimate drug sales, warranting “severe criminal penalties.” The defendant is not entitled to dictate the Government’s charging decisions, or the findings of the grand jury, in this regard.

Finally, the defendant’s reliance on the passage of the SUPPORT Act to buttress his claim that he is exempt from prosecution under Section 841 is entirely misplaced. His argument rests on the faulty premise that Section 841 did not apply to him before the passage of the SUPPORT Act, and that, therefore, Congress’s failure to amend Section 841 to so apply is indicative of a Congressional intent to exempt him from liability. (*See* Mot. at 25.) For all of the reasons discussed above, Section 841 has never categorically exempted anyone – including the defendant – from liability based on his or her status. Courts consistently have reaffirmed this plain-language interpretation of Section 841. Because the CSA is clear that Section 841 applies to “any person,” and because courts universally have interpreted Section 841 in a way that is consistent with its plain meaning, Congress did not need to amend Section 841 in order for it to apply to the defendant. Sections 841 and 846 apply and have always applied to CEOs of pharmaceutical companies who conspire to distribute controlled substances not for legitimate medical purposes. The drug laws are tethered to criminal conduct, not to professional standing.

II. Sections 841 and 846 Are Not Unconstitutionally Vague as Applied to the Defendant

A. Applicable Law

“The void-for-vagueness doctrine requires that a penal statute define the criminal offense with sufficient definiteness that ordinary people can understand what conduct is prohibited and in

a manner that does not encourage arbitrary and discriminatory enforcement.” *United States v. Halloran*, 821 F.3d 321, 337 (2d Cir. 2016) (quotation marks omitted). “Although a law has to provide minimal guidelines in the form of explicit standards regarding what conduct is unlawful, it need not achieve meticulous specificity, which would come at the cost of flexibility and reasonable breadth.” *United States v. Rosen*, 716 F.3d 691, 699 (2d Cir. 2013) (internal quotation marks omitted), *abrogated on other grounds by McDonnell v. United States*, 136 S. Ct. 2355 (2016). Even in the absence of sufficient standards, however, “a statute will survive an as-applied vagueness challenge if the conduct at issue falls within the core of the statute’s prohibition, so that the enforcement before the court was not the result of the unfettered latitude that law enforcement officers and factfinders might have in other, hypothetical applications of the statute.” *United States v. Farhane*, 634 F.3d 127, 139-40 (2d Cir. 2011) (internal quotation marks omitted); *see Maynard v. Cartwright*, 486 U.S. 356, 361 (1988) (“Objections to vagueness under the Due Process Clause rest on the lack of notice, and hence may be overcome in any specific case where reasonable persons would know that their conduct is at risk.”); *United States v. Rybicki*, 354 F.3d 124, 132 (2d Cir. 2003) (holding that a statute need only “give[] the person of ordinary intelligence a reasonable opportunity to know” the charged conduct is illegal). In analyzing void-for-vagueness challenges, “it is immaterial [if] there is no litigated fact pattern precisely [on] point.” *United States v. Kinzler*, 55 F.3d 70, 74 (2d Cir. 1995) (citations and internal quotation marks omitted).

B. Discussion

The defendant had ample notice that his conduct was illegal, and Sections 841 and 846 do not encourage arbitrary enforcement. As an initial matter, the defendant’s claim that this case represents a novel prosecution is immaterial to this Court’s analysis. *See Kinzler*, 55 F.3d at 74. And for many of the same reasons that Sections 841 and 846 in fact do apply to the defendant, the

defendant was on notice that those statutes apply to him. As set forth in detail above, the plain language of Section 841 sweeps broadly, applying to “any person.” No court has ever granted the type of blanket exemption to criminal liability under Sections 841 and 846 that the defendant seeks. To the contrary, courts considering prosecutions of individuals employed within the legal controlled substances distribution chain consistently have concluded that any person who knowingly distributes controlled substances outside of that legal chain – in other words, who distributes controlled substances knowing that their distribution is not based on a legitimate medical need for those controlled substances – is subject to prosecution under Sections 841 and 846.

The defendant’s argument reduces to a claim that he believed that, because of his status as a pharmaceutical executive, he was free to direct the distribution of controlled substances as he pleased, with no possibility of facing the same penalties as any other person who undertook the same actions. The notion that in the face of employees telling him that specific doctors were diverting controlled substances, the defendant believed that he could lawfully direct those employees to continue shipping oxycodone and fentanyl to fill those doctors’ prescriptions, is beyond credulity. The defendant even acknowledges that “it is clear and inescapable that when a medical practitioner issues a prescription not for a medical purpose and not in the course of his professional practice, he violates the statute.” (Mot. at 28 (citing *United States v. Jobe*, 487 F.2d 268, 269 (10th Cir. 1973).) It is equally clear and inescapable that when a pharmaceutical executive ships orders for controlled substances, knowing that they will be used to fill prescriptions written not for a legitimate medical purpose, he violates Section 841.

That the defendant has not identified a single case holding that Section 841 or 846 is unconstitutionally vague as applied to any defendant is telling. He has identified no such case

because any “reasonable person reading § 841(a)(1) is on notice that distributing controlled substances violates the CSA unless such distribution fits within an exception.” *United States v. Birbragher*, 603 F.3d 478, 488 (8th Cir. 2010). The exceptions to Section 841’s sweep are narrow, and “are sufficiently clear that the speculative danger of arbitrary enforcement does not render [them] void for vagueness.” *Id.* at 489 (citing *United States v. DeBoer*, 966 F.2d 1066, 1068-69 (6th Cir. 1992); *United States v. Rosenberg*, 515 F.2d 190, 197-98 (9th Cir. 1975); *United States v. Collier*, 478 F.2d 268, 272 (5th Cir. 1973)); *see also Quinones*, 536 F. Supp. 2d at 274 (“By its terms, § 841(a)(1) creates a sweeping prohibition on distribution of controlled substances, subject to a relatively narrow exception for distribution within the usual scope of professional practice.”). It naturally follows that the applicability of this broad and plainly worded statute is clear: it applies to “any person,” the defendant being no exception.

CONCLUSION

Accordingly, the Government respectfully requests that the Court deny the defendant’s motion to dismiss Count One of the Indictment.

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October 22, 2019

Respectfully submitted,

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